DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 20, 2015

BioVision Technologies, LLC
Mr. David Sanso
President
221 Corporate Circle, Unit H
Golden, Colorado 80401

Re: K143705
Trade/Device Name: NeedleCam HD™ Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: January 29, 2015
Received: January 30, 2015

Dear Mr. Sanso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143705

Device Name
NeedleCam HD™ Visualization System

Indications for Use *(Describe)*
NeedleCam HD™ Visualization System

Indications for Use: The NeedleCam HD™ Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

This is the same intended use as for a previously cleared device - the BioVision Technologies SurgView™ Integrated Visualization System (K082293).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Needle Cam HD™ Visualization System
Special 510(k) Submission

SPECIAL 510(k) SUMMARY

Submission Information

Date Prepared: December 22, 2014

Applicant: BioVision Technologies, LLC.
Address: 221 Corporate Circle Unit H
Golden, Colorado 80401

Telephone Number: 303-237-9608

Submitter's Contact: David Sanso, President

Device Information

Proprietary Name: NeedleCam HD™ Visualization System

Common Name: Arthroscope/Endoscope

Classification Name: Arthroscope / Endoscope and Accessories

Regulation Number: 21 CFR §888.1100, HRX
21 CFR §876.1500, GCJ

Regulatory Class: II

Predicate Device

BioVision Technologies SurgView™ Integrated Visualization System (K082293)

Device Description

Name of the Device: NeedleCam HD™ Visualization System

NeedleCam HD™ Visualization System is comprised of an Image Capture Box, a Camera Handpiece (including an LED light source) that captures still images and full resolution video, and External Power Supply. The camera has a quick-release optical connector that adapts to a wide variety of Bio Vision Technologies' surgical endoscopes. The device is used with an endoscope to visualize and illuminate an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures.

The BioVision endoscopes and supplemental instruments that were approved with the predicate SurgView Visualization System have not been changed.

Statement of Intended Use

The system is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and the cervix.

NeedleCam HD System Components and Accessories

The NeedleCam HD Visualization System is intended to be used with BioVision endoscopes. The following is a listing of the current compatible scopes, along with the applicable 510(k) clearance numbers.

Part Number	Description	510(k) Number
BVTKIT72-0L065	OnPoint 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L165	BioVision NeedleView 0 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-0L1A0	BioVision NeedleView 0 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R165	BioVision NeedleView 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R1A0	BioVision NeedleView 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R265	InnerVue II 10 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT72-1R2A0	InnerVue II 10 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293

BVTKIT75-3R165	BioVision NeedleView 30 deg, 65mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT75-3R1A0	BioVision NeedleView 30 deg, 100mm Scope kit (including scope, cannula, obturator, trocar and plug)	K082293
BVTKIT82-34001	BioVision NeedleView CH 3.4mm Scope Kit (including scope, cannula, dilator, tuohy needles, scalpel and guidewire	K141326

Comparison to Predicate Device

The table below shows relevant similarities and differences between the NeedleCam HD™ Visualization System and its predicate device – SurgView™ Integrated Visualization System (K082293).

APPLICANT DEVICE: NeedleCam HD™ Visualization System

PREDICATE DEVICE: SurgView™ Visualization System (K082293)

NOTE: **Relevant similarities are identified in bold text.**
Relevant differences are identified in underlined text.

PREDICATE COMPARISON CHART

I. GENERAL CHARACTERISTICS			PREDICATE DEVICE
ITEM	**FEATURE**	**NeedleCam HD Visualization System**	**SurgView™ Visualization System K082293**
1	**Device Description**	NeedleCam HD Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **An Image Capture Box that includes image processor and** external power supply) 2. **Camera handpiece** including a LED light source. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture USB System 5. **Video Outputs for external monitor**	The SurgView™ Visualization System **is a video endoscope/arthroscope imaging system consisting of the following components:** 1. **A Light Source/Display/Image Capture device that includes** an internal monitor, **image processor,** Xenon light source and internal power supply**.** 2. **Camera handpiece**. 3. **A semi-rigid Fiberoptic Scope in a variety of diameters, lengths, and viewing angles. Supplemental instruments for the scope include a cannula, trocar, obturator, and cannula plug.** 4. Media Capture CF Card System 5. **Video output for external monitor.**

2	Intended Use	Needle Cam HD™ **Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.	The SurgView™ **Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix**.
3	Materials Used	**Plastic enclosure, media capture board**, **plastic camera cable.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**	**Plastic enclosure,** metal plate, **media capture board**, **plastic camera cable**, and fiber optic cable**.** **Scopes & instruments - Stainless Steel for Scope Shaft; Fiber Optics for light transmission**
4	Labeling (Single Use/Reusable)	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**	**Image capture box and camera handpiece: Reusable.** **Scopes & instruments: Sterile, Single Use**
5	Image acquisition	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**	**Image acquisition is achieved through an endoscope attached to a camera handpiece. The endoscope is in the sterile field while the handpiece remains non-sterile. A barrier is provided to preserve the sterile field.**
6	Connectivity	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The LED light source is included in the camera handpiece. **The camera cable connects to the image capture device using a single electrical connector.**	**The endoscope, camera handpiece, cable, illumination source and image processor connections allow functional coupling of the components while providing safe and reliable connections, in particular those related to electrical safety for the user and patient. The endoscope attached to the camera handpiece using a quick release connection.** The fiberoptic bundle is integrated with the camera cable. **The camera cable connects to the** light source**/image capture device using a single hybrid (electrical/optical) connector.**
7	Image processing	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**	**The image is digitally processed to allow further manipulation, capture, printing, and multiple displays.**
8	Image display (s)	**External monitor connection**	Internal monitor display with **external monitor connection.**
9	Data Entry	**Session information entered via external keyboard**	**Session information entered via external keyboard**

10	Data storage	Image and video storage to USB device	Image and video storage to Compact Flash™ cards.
11	Where used	**Hospital / Doctor's office**	**Hospital / Doctor's office**
II. CHARACTERISTICS OF THE LIGHT SOURCE			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System K082293**
1	Illumination	**Illumination is achieved via** an internal LED light source. **The** LED **light source is an integral part of the device.** The LED is internal to the camera handpiece. **LED and Xenon usable light output is equivalent.**	**Illumination is achieved via** a fiberoptic bundle attached to the endoscope**. The** Xenon **light source is an integral part of the device.** The Xenon light source is internal to the image capture box. **LED and Xenon usable light output is equivalent.**
2	Type of light source	LED	Xenon
3	Lamp power rating	1W	35W
4	Rated lamp life	20,000 hours	3,000 hours
5	Luminous intensity as measured at scope output	**4-6 lumens**	**4-6 lumens**
III. CHARACTERISTICS OF THE CAMERA			
ITEM	FEATURE	**NeedleCam HD™ Visualization System**	**SurgView™ Visualization System**
1	Camera sensor	**¼" CCD**	**¼" CCD**
2	Sensor resolution	**768(H) x 494(V) pixels**	**768(H) x 494(V) pixels**
3	Camera resolution	**480 lines, interlaced**	**480 lines, interlaced**
4	Camera sterility	**Non sterile. Drape is used for sterile field preservation.**	**Non sterile. Drape is used for sterile field preservation.**
5	Endoscope coupler	**Built-in**	**Built-in**

Conclusion: Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision NeedleCam HD ™ Visualization System is substantially equivalent to the predicate device listed in this submission.

The upgrades were completed to incorporate the improved light source options provided by LED lighting. The industry standard for media storage has moved from CF cards to USB technology. Additionally, analog television technology has been replaced by digital television technology.

Summary of Technologies

The technological characteristics of the BioVision NeedleCam HD™ Visualization System are similar to its predicate device – BioVision SurgView™ Visualization System (K082293). The indications and contraindications listed in this submission are in congruence between these devices. The modifications are incremental changes to the predicate image capture box and camera handpiece that do not affect safety and effectiveness of the modified device. The modifications are the following:

1) Update the image capture box to the current standard USB storage device;
2) Update the existing video format to the current digital format.
3) The camera handpiece has been upgraded with an LED light source.

We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Performance Testing

Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision NeedleCam HD™ Visualization System and its predicate device – BioVision SurgView™ Visualization System (K082293).

Safety testing was completed to ANSI/AAMI ES 60601-1:2005 (3rd edition) on the BioVision NeedleCam HD™ Visualization System. Additionally software validation was completed on the system.

Clinical Testing

Clinical testing was not used to prove substantial equivalence. Establishment of equivalence is based on similarities of intended use, design, physical characteristics and geometry between the BioVision Needle Cam HD and its predicate device.

Conclusion

Based on the evaluation of the performance characteristics, construction, manufacturing processes, and indications of use, BioVision Technologies has concluded that the BioVision Needle Cam HD™ Visualization System is substantially equivalent to the predicate device listed above. In all cases, the characteristics of this device are identical or similar to the predicate device as they relate to the intended uses or application. BioVision Technologies has also determined that the modification is an incremental change to the existing device that does not affect safety and effectiveness of the device.